Biotechnology Industry Organization

April 8, 2013

Centers for Medicare & Medicaid Services
Office of Strategic Operations and Regulatory Affairs
Division of Regulations Development
Room C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: Comments on the estimated burden of complying with Section 6002 of the Affordable Care Act.

Dear Sir/Madam:

The Biotechnology Industry Organization (BIO) thanks the Centers for Medicare & Medicaid Services (CMS) for the opportunity to submit comments on the estimated burden of complying with the final rule as well as any other ways to enhance the quality, utility, and clarity of the information to be collected.

BIO represents more than 1,100 biotechnology companies, academic institutions, state biotechnology centers and related organizations across the United States and in more than 30 other nations. BIO members are involved in the research and development of innovative healthcare, agricultural, industrial and environmental biotechnology products, thereby expanding the boundaries of science to benefit humanity by providing better healthcare, enhanced agriculture, and a cleaner and safer environment.

As stated in our previous comments to CMS, BIO supports the goals of the Affordable Care Act (ACA) in providing greater transparency regarding financial relationships with healthcare providers and we recognize the significant challenges that were presented in implementation of these ACA provisions. We are also pleased to see that CMS is taking additional steps to minimize the information collection burden on manufacturers.

Below are some general comments about the rule, followed by more specific comments regarding particular provisions.

GENERAL COMMENTS:

Facilitating Revisions and Corrections

- It is not clear whether revisions and corrections to specific rows in the reporting template would require submission of an entirely new report, or only specific rows. We recommend that CMS allow manufacturers the option to submit corrected rows, rather

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than an entire report. To make that possible, manufacturers should be given the flexibility to provide either a unique transaction identifier in the initial submissions and any subsequent submissions, or the manufacturer should have the option of utilizing a unique line identifier supplied by CMS for each record. That way, manufacturers can simply submit the revised record with the unique identifier, and not overwhelm the CMS submission portal with unchanged records.

SPECIFIC COMMENTS:

Non-Research Payment Template

Row 27: Name of Associated Drug, Device, Biological, or Medical Supply

- The final rule provides that "Applicable manufacturers may report up to **five** covered drugs, devices, biologicals or medical supplies related to each payment or other transfer of value."[1][emphasis added]. The definition/description does not describe how reporting entities should separate the names of multiple products when they are reported on this row. We recommend CMS specify how names should be separated from each other.

- The "Required" column in this row indicates the name must be provided. However, in the final rule, the agency indicated that, "[f]or devices and medical supplies, §403.904(c)(8)(ii) allows reporting of either the name under which the device or medical supply is marketed, or the therapeutic area or product category."[2] We recommend that CMS clarify in the instructions for this row that the requirement to provide the name does not apply to devices and medical supplies.

Row 28: NDC of Associated Drug, Device, Biological, or Medical Supply

- National Drug Codes (NDCs) are very granular in terms of dosage and packaging, resulting in multiple NDCs for a single product, and may change over time. Transfers of value to covered recipients by applicable manufacturers are not tracked at this level of detail, nor is it relevant. Since Row 27 already captures the name of the associated drug, device, biological or medical supply, and applicable manufacturers may report up to five covered products (as described above), we recommend that CMS omit this field since it is redundant, does not add value for consumers, and will not enable CMS to "roll up" or aggregate the data per covered product.

  In the alternative, the Data Element Size for this row indicates that it will accommodate only 12 characters. As noted, Row 27 allows the inclusion of up to five drugs, devices, biological or supplies, each of which will have a unique NDC. We recommend that CMS modify this row to allow the inclusion of up to five NDCs, that CMS provide clear instruction on how the NDCs should be separated, and that the allowed number of characters be expanded to accommodate five NDCs, with whatever separating value that CMS requires.

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[1] 42 CFR 403,904(c)(8)

[2] 74 Federal Register 9475 (Feb. 8, 2013)

Row 39: Nature of Payment or Transfer of Value

- The "Values" listed for this row do not include a category for "Other." In the final rule, CMS indicates that the "gift" category "is a general category, which will often include anything provided to a covered recipient that does not fit into another category." Since some transfers of value to physicians or teaching hospitals will not fall into one of the enumerated categories, but do not constitute a gift per se, we recommend that CMS establish an "Other" category to capture such transfers of value.

Research Payment Template

Rows 53 – 56: Multiyear Payment Structure Indicator, Total Number of Years for this Research Payment, Total Number of Years for this Research Project, Total Research Budget of this Project

- None of these fields were included in the Proposed Rule; as such, there was no opportunity to review and provide comment. Similarly, these fields are not addressed in the Final Rule. While companies may plan for studies to last for particular lengths of time, the reality is that such factors change constantly. Depending on enrollment rates at different sites, a study that was intended for completion within a particular time frame may be extended into the following year(s), which is not discernible at the time a payment is made. Work may have been completed during the initial calendar year, but payments are not made until the subsequent year. Clinical studies are often global in nature with global budgets (i.e., the project budget includes the cost of payments to sites outside the United States). As written, the definition/description implies that CMS would like the global study budget included in this field, which seems to be beyond the scope of the relevant ACA provisions. We recommend that CMS omit these fields since they were not adequately proposed or reviewed during the notice and comment period.

Row 58: Name of Study

- The Data Element Size for this row indicates that it will accommodate only 100 characters. We recommend that CMS modify this row to accommodate up to 500 characters, since many study titles far exceed 100 characters.

Rows 64 – 65: Expenditure Category, Expenditure Category Percentage

- Since companies may report a lump sum for research payments, these fields are extraneous, albeit optional. We recommend that these fields be omitted.

Conclusion

BIO appreciates this opportunity to comment on Section 6002 of the Affordable Care Act, as these issues are of significant importance to our member companies. If you have any questions regarding these comments, please contact me at 202-962-6673 or sdennis@bio.org.

Sincerely,

Sandi Dennis

Sandra Dennis
Deputy General Counsel, Health Care
Biotechnology Industry Organization